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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,681	09/29/2003	Stuart Peirson	4586-4001	5505

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EXAMINER	
AGRAWAL, RITESH	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
05/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,681	PEIRSON ET AL.	
	Examiner	Art Unit	
	Ritesh Agrawal	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006 and 05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-14,22-33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21,34,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment and request for reconsideration in the communication filed on 12/01/06 and 03/05/07 are acknowledged and the amendments entered.

Claims 1-37 are currently pending and claims 15-21 and 34 and 36-37 are under consideration.

Withdrawn Rejections

2. The prior rejections under 35 U.S.C. 112, 2nd paragraph are withdrawn in light of applicants' amendments filed 12/01/06 and 03/0507.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 15-18, 34, and 36-37 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Ward et al. (US Patent Publication # 2003/0044826) with a priority date of August 21st, 2001.

The claims are drawn to a system for analyzing data from a polymerase chain reaction. The system includes:

a) A memory

b) A unit for calculating a logarithm of the signal

c) A reaction efficiency calculator

d) A selector for selecting a set of cycles

e) An estimator for estimating slope

Ward et al. disclose a system for quantifying DNA from a polymerase chain reaction (abstract, lines 1-3). Their system includes memory (see, for example, figure 8, module 830). Their system calculates a logarithm of the signal (see, for example, figures 1, 2, or 7a). They disclose calculating amplification efficiency (see paragraph 67, lines 9-10) and provide an equation for the calculation (paragraph 85, lines 2-3). They disclose selecting "threshold cycles" (paragraph 83, lines 6-8). They also disclose that their system estimates slopes (claim 23).

With respect to claim 16 with the additional limitation that the signal is a fluorescent signal, Ward et al. disclose their use of fluorescence (see, for example, claim 25).

With respect to claim 17 with the additional limitation that the estimator carry out linear regression, Ward et al disclose the limitation (see, for example, paragraph 82, line 1).

With respect to claim 18, with the limitation that the estimator average the difference of the signal between adjacent cycles, performing a linear regression is a

method of average the difference between data points and therefore Ward et al. disclose the limitation of claim 18 as cited above for claim 17.

With respect to claim 34 with the additional limitation that the calculations be carried out in real-time, while the reaction proceeds, Ward et al. disclose at least one embodiment of their invention that is able to carry out calculations in real-time. They disclose that their data processing module, which carries out the calculations, can receive data directly from the collection module (see paragraph 91, lines 1-4) which receives data in real-time, while the reaction module is in operation (see paragraph 89, lines 4-6).

With respect to claim 36, with the additional limitation of a measuring unit, Ward et al. disclose a data collection module that detects and measures fluorescence (see paragraph 89, lines 1-4).

With respect to claim 37, with the additional limitation that the system be applicable to multiple samples, Ward et al. disclose that the system can be run on a plurality of reactions by averaging results from the plurality of reactions (paragraph 7, lines 11-14).

This rejection is maintained from the previous Office action. Applicants' arguments have been fully considered, but they are not found persuasive.

Applicants argue:

> There is thus no disclosure or suggestion in Ward of an efficiency calculator which calculates reaction efficiency from a dependence of the fluorescence signal on the cycle number, let alone a disclosure or suggestion of the efficiency calculator including an estimator for estimating the slope of the dependence of the logarithm on the cycle number (remarks, page 17, 1st paragraph).

Although applicants correctly cite the claim limitations in reading: "calculating a reaction efficiency from a dependence of the signal on the cycle number", applicants appear to be reading additional limitations into the claims that are not found in the claims themselves. Applicants appear to argue that because Ward does not disclose calculating a reaction efficiency *directly* from a dependence of the signal on the cycle number (remarks, page 18, 1st paragraph), Ward does not anticipate their claims. As highlighted, applicants' claims do not require such a limitation. Applicants' claims only require the consideration of such a dependence of signal on cycle number in the process of determining reaction efficiency. Applicants' claims do not preclude the inclusion of further information beyond that which is found in the reaction graph itself. Ward determines slopes of lines that represent changes in the logarithm of the fluorescent signal over various cycles (a dependence of fluorescent signal on cycle number) to determine threshold cycles (for example, figure 6; paragraph 12) and then uses the logarithm of the fluorescence intensities at the selected threshold cycles to determine reaction efficiency by comparing the observed signal intensities to those from a standard curve (for example, paragraph 67, last line; paragraph 79). Thus, Ward determines slopes that represent a dependence of the logarithm of signal intensity on cycle number and since this dependence information is used in Ward's calculation of reaction efficiency, Ward is calculating reaction efficiency from this dependence information.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to claims 15-18, 34, and 36-37 above, and further in view of Peirson et al. (Nucleic Acids Research, Vol. 31, pages 1-7, July, 2003).

The claims are drawn to the method of claim 15 with the additional limitation of a selector wherein the set of cycles is centered around the cycle with a fluorescent level closest to the average of the noise and saturation levels.

Ward et al. disclose a system with the limitations of claim 15 as cited above.

However, Ward et al. do not disclose the selector of claim 19 wherein the set of selected cycles is centered around the cycle with a fluorescent level closest to the average of the noise and saturation levels.

Peirson et al. disclose a selector wherein the selected cycles are centered around the cycle(s) with fluorescent levels closest to the average of the noise and saturation levels (page 3, 1st paragraph, lines 1-2 and equation therebelow). While Peirson et al. do not explicitly disclose that this midpoint would represent a single cycle for an odd number of total cycles or two cycles for an even number of total cycles, by definition, the midpoint for an odd number of cycles is a single cycle and the midpoint for an even number of cycles is two cycles.

With respect to claim 20, Peirson et al. disclose linear regression around the midpoint (page 3, 2nd paragraph, lines 6-8).

With respect to claim 21, in the absence of an explicit definition for the term coefficient of determination, it will be interpreted to mean the best combination of slope and R^2 values. Ward et al. disclose selecting points for analysis based upon maximizing these parameters (see, for example, claim 23).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of Peirson et al. to use it along with the

system of Ward et al. One of ordinary skill in the art would have been motivated to modify the method of Peirson et al., because the system of Ward et al. provides an integrated system in which to carry out all the steps from the acquisition of PCR data, to obtaining a final quantitation of DNA. In providing a single, integrated, automated system, the combined system would eliminate the need for initial analysis of amplification data via other means (see, for example, the need for initial analysis via SDS 1.7, Peirson et al. page 2, 2nd paragraph, lines 1-3). In so doing, it would allow for the entire analysis in a user-independent manner (Ward et al., paragraph 91, lines 12-15), which could improve the performance and accuracy of the calculation (Ward et al., paragraph 40, lines 5-6). Hence, by integrating the methodology of Peirson et al. into the system of Ward et al. one would obtain better results and the analysis would take less of their time.

This rejection is maintained from the previous Office action. Applicants have not addressed this rejection beyond the base reference (as rebutted under the 102 rejection, above).

Conclusion

5. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER